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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,920	01/30/2002	Tadashi Ookawa	396.41133X00	4634

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EXAMINER

MAIER, LEIGH C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

### Office Action Summary

**Application No.**

10/058,920

**Applicant(s)**

OOKAWA ET AL.

**Examiner**

Leigh C. Maier

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on November 17, 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11,12,15,16 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11,12,15,16 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 1-10, 13, 14, 17, and 18 have been cancelled. Claims 11, 15, 16, and 19 have been amended. Claims 11, 12, 15, 16, and 19 are pending. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112 – 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The amended claim recites a degree of acetylation range of 0.3 to 0.8. The specification discusses acetylation at page 13, second full paragraph, and appears to support two ranges: (1) 0.3 or higher, which is equal to 0.3 to 1.0; and (2) 0.4 to 0.8. the examiner does not find support in the specification for the added range of 0.3 to 0.8.

***Claim Rejections - 35 USC § 112 – 2<sup>nd</sup> paragraph***

Claims 11, 12, 15, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites “controlling an acetylation degree of an amino group of a polyglycosamine to 0.3 to 0.8 to enhance a [sic] water solubility thereof.” One of the polysacchararide species recited in claim 15 is polygalactosamine. Polygalactosamine is a natural product that is found in nature as a free amine. From claim 11, it appears that some acetylation is required. However acetylating the unacetylated polygalactosamine would not *enhance* water solubility. These conflicting limitations render the claims vague and indefinite.

***Claim Rejections - 35 USC § 102***

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by HORTON et al (Carbohydr. Res., 1973).

The reference discloses chitosan derivatives (which, by definition, are also chitin derivatives) wherein more than 40% of the primary alcohol groups are oxidized into carboxyl groups. The chitosan derivatives have a molecular weight of about 400 kD to about 580 kD. See page 175, the reaction scheme and the first full paragraph. The claim is thus anticipated.

***Claim Rejections - 35 USC § 103***

Claims 11, 12, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHANG et al (J. Carbohyd. Chem., 1996) and BRAGD et al (US 6,608,229).

The claims have been amended to recite a process for oxidizing a polyglycosamine comprising controlling the degree of acetylation followed by oxidation with a hypochlorous acid/salt in the presence of a nitroxyl compound in the absence of bromine/bromide or iodine/iodide. Claim 19 is drawn to a particular oxidized polyglycosamine product.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground of rejection.

CHANG teaches the selective oxidation of the primary alcohol moiety of several polysaccharides, including chitin and chitosan, using TEMPO, NaBr, and NaOCL at pH of 10.8. See Table 1 and page 828. It is also noted that the reference teaches the oxidation of both of these products and notes that chitin is insoluble whereas the deacetylated derivative, chitosan, is soluble. The oxidized products have utility as gums, gels, and films. See abstract. The reference does not teach the oxidation in the absence of bromine/bromide or iodine/iodide.

BRAGD teaches the oxidation of polysaccharides with TEMPO and hypochlorite at pH 8.5 in the absence of bromine/bromide or iodine/iodide. This process has the advantage of lower pH than without bromide with no substantial depolymerization at optimum pH. See col 1, lines 36-58 and the example. The reference specifically suggests the use of chitins as the polysaccharide substrate.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare oxidized chitosan using the process disclosed by BRAGD for the

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art disclosed utility in preparing gums, films, and gels. The artisan would be motivated to employ this process because it allows for better control over the final molecular weight as BRAGD teaches that this process proceeds without depolymerization. One of ordinary skill would recognize that chitosan is deacetylated chitin. In the absence of a showing of criticality in the recited deacetylation range, it would be within the scope of the artisan to use routine experimentation to optimize the degree of acetylation to achieve solubility in order to achieve a homogeneous reaction solution.

*Examiner's hours, phone & fax numbers*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.



Leigh C. Maier  
Patent Examiner  
February 20, 2003